

00927406 12304
10927406 12304

WHAT IS CLAIMED IS:

1. A protein composition, free from total cell components, the protein being characterized as having a molecular weight of about 13 kD, as determined by sodium dodecyl sulfate polyacrylamide gel electrophoresis (SDS/PAGE), and being isolatable from *B. burgdorferi*.
2. The protein composition of claim 1, wherein the composition further comprises *B. burgdorferi* outer membrane proteins OspA, OspB, OspC or OspD, in combination with a pharmacologically acceptable diluent or carrier.
3. A purified protein having the following characteristics:
 - (a) being isolatable from *B. burgdorferi*;
 - (b) being present on the surface of *B. burgdorferi* cells that lack the outer membrane proteins OspA, OspB, OspC and OspD;
 - (c) being sensitive to cleavage with proteinase K;
 - (d) having a molecular weight of about 13 kD, as determined by SDS/PAGE;
 - (e) having binding affinity for the monoclonal antibodies termed 15G6 and 7D4.
4. The purified protein of claim 3, further defined as being isolated from *B. burgdorferi* cells.

5. The purified protein of claim 3, further defined as being a recombinant protein obtained from a recombinant host cell that includes a nucleic acid segment that expresses said protein.

6. The purified protein of claim 3, in combination with a pharmacologically acceptable diluent or carrier.

7. The purified protein of claim 3, linked to a detectable label, the label being a radioactive label, a flourogenic label, a nuclear magnetic spin resonance label, biotin or an enzyme that generates a colored product upon contact with a chromogenic substrate.

8. An antibody that has binding affinity for the protein of claim 3.

9. The antibody of claim 8, linked to a detectable label, the label being a radioactive label, a flourogenic label, a nuclear magnetic spin resonance label, biotin or an enzyme that generates a colored product upon contact with a chromogenic substrate.

10. The antibody of claim 9, linked to an alkaline phosphatase, hydrogen peroxidase or glucose oxidase enzyme.

11. The antibody of claim 8, further defined as a monoclonal antibody.

12. The antibody of claim 11, further defined as the monoclonal antibody 15G6 or 7D4.

13. A method for detecting *B. burgdorferi* in a sample, comprising contacting a sample suspected of containing *B. burgdorferi* with a first antibody in accordance with claim 8, under conditions effective to allow the formation of immune complexes, and detecting the immune complexes so formed.

14. The method of claim 13, wherein the first antibody is the monoclonal antibody 15G6 or 7D4.

15. The method of claim 13, wherein the first antibody is linked to a detectable label and the immune complexes are detected by detecting the presence of the label.

16. The method of claim 13, wherein the immune complexes are detected by means of a second antibody linked to a detectable label, the second antibody having binding affinity for said first antibody.

17. The method of claim 13, further defined as a method of diagnosing Lyme Disease, wherein the sample suspected of containing *B. burgdorferi* is a clinical sample obtained from a patient suspected of having Lyme Disease and the detection of immune complexes is indicative of a patient with Lyme Disease.

18. A method for detecting antibodies to *B. burgdorferi*, comprising contacting a sample suspected of containing antibodies to *B. burgdorferi* with a protein in accordance with claim 3,

under conditions effective to allow the formation of immune complexes, and detecting the immune complexes so formed.

19. The method of claim 18, wherein said protein is linked to a detectable label and the immune complexes are detected by detecting the presence of the label.

20. The method of claim 18, wherein the immune complexes are detected by means of a second antibody linked to a detectable label, the second antibody having binding affinity for said protein.

21. The method of claim 18, wherein the immune complexes are detected by means of a second antibody linked to a detectable label, the second antibody having binding affinity for the first, anti-*B. burgdorferi* antibodies.

22. The method of claim 18, further defined as a method of diagnosing Lyme Disease, wherein the sample suspected of containing antibodies to *B. burgdorferi* is a clinical sample obtained from a patient suspected of having Lyme Disease and the detection of immune complexes is indicative of a patient with Lyme Disease.

23. An immunodetection kit comprising, in suitable container means, a protein in accordance with claim 3 or a first antibody in accordance with claim 8, and an immunodetection reagent.

24. The immunodetection kit of claim 23, wherein the immunodetection reagent is a detectable label that is linked to said protein or said first antibody.

25. The immunodetection kit of claim 23, wherein the immunodetection reagent is a detectable label that is linked to a second antibody that has binding affinity for said protein or said first antibody.

26. The immunodetection kit of claim 23, wherein the immunodetection reagent is a detectable label that is linked to a second antibody that has binding affinity for a human antibody.

27. A method of generating an immune response, comprising administering to an animal a pharmaceutically acceptable composition comprising an immunologically effective amount of a protein that has a molecular weight of about 13 kD, as determined by SDS/PAGE, and is isolatable from *B. burgdorferi*.

28. The method of claim 27, wherein the composition further comprises a *B. burgdorferi* OspA, OspB, OspC or OspD protein.

29. The method of claim 27, wherein the 13 kD protein is a recombinant protein.

30. A mutant *B. burgdorferi* that lacks the OspA, OspB, OspC and OspD proteins.